

## REMARKS

Claims 1-6, 8-23, 25-43 and 51-58 are pending in the application. Claims 7, 24, 44-50 were previously canceled without prejudice. Claims 17, 39, 43, 52 and 56 are currently amended. The amendments do not present any new matter. Reconsideration and allowance of the application, as amended, are respectfully requested.

### I. Withdrawn Rejections and Objections

Applicant kindly acknowledges that the rejection of claims under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2004/0126281 A1 to Morrison (“Morrison”) has been withdrawn, and that the rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Morrison has been withdrawn.

Applicant further kindly acknowledges that the rejection of claims under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 5,635,403 to Bailey (“Bailey”) and the rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Bailey has been withdrawn.

Applicant also kindly acknowledges that the rejection of claims 51-55 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Pub. No. US 2002/0045272 A1 to McDevitt *et al.* (“McDevitt”) has been withdrawn. Instead, these claims are currently rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt and in view of Bailey.

Applicant also kindly acknowledges that the rejection of claim 56 under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt has been withdrawn. Instead, this claim is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt and in view of Bailey.

Applicant also kindly acknowledges that the rejection of claims 16 and 35 under 35 U.S.C. §103(a) as allegedly being unpatentable over Bailey has been withdrawn. Instead, these claims are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Bailey in view of U.S. Patent No. 5,935,426 to Giordano *et al.* (“Giordano”).

Applicant also kindly acknowledges that the claim objections of the March 9, 2007 Office Action have also been withdrawn, and that the rejection of claims 4 and 21 under 35 U.S.C. §112 ¶2 have also been withdrawn.

**II. Claims 39-42 and 52-55 Satisfy §112 ¶2**

Applicant respectfully submits that the amendments to claims 39 render the rejection of claims 39-42 and 52-55 under 35 U.S.C. §112 ¶2 moot.

It is stated in the final Office Action that “It is not clear how the claimed vial relates to the claimed invention because claim 39 does not positively recite that the claimed invention comprises a vial.” Final Office Action (p. 2). Claim 39 as amended positively recites a vial, thereby rendering the rejection of claims 39-42 is moot. Further, Applicant notes that simply because a claim may recite a sample does not render that claim indefinite, particularly considering that the preamble of independent claim 18 is directed to “a system for preparing a biological specimen sample” and claim limitations that refer to a sample do so to recite the context or environment to which embodiments apply.

It is also stated in the final Office Action that claims 52-55 do not positively recite that the claimed apparatus comprises the slide processor. Final Office Action (p. 3). Claim 52 is amended to recite that the filter being adapted for use with a slide processor to permit the slide processor to determine whether the filter was previously utilized based on the data in the data storage device, thereby rendering the rejection of claims 52-55 moot.

Accordingly, Applicant respectfully requests that the rejection of claims 39-42 and 52-55 under 35 U.S.C. §112¶2 be withdrawn.

**III. Claims 1-6, 11, 12, 14, 15, 18-23, 29-31, 33, 34 and 36-42 Are Novel Over McDevitt**

Independent claims 1 and 18 and respective dependent claims 2-6, 11, 12, 14, 15, 19-23, 29-31, 33, 34 and 36-42 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by McDevitt. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131. Applicant respectfully traverses the rejection since McDevitt fails to anticipate any claim of the subject application.

Initially, McDevitt fails to disclose, teach or suggest the combination of “a data storage device attached to or positioned within the container” and “wherein data related to the filter is stored in the data storage device” as recited in claims 1 and 18 and wherein such data related to the filter “can be retrieved from” the data storage device as recited in claim 18.

Applicant believes it would be helpful to clarify statements in the final Office Action regarding what Applicant allegedly states as being disclosed by McDevitt. It is stated in the final

Office Action that “As conceded by Applicant and disclosed in [0573] of McDevitt et al., the bar code can be used to identify the type of sensor array, including the type of test being conducted and the identity of the analyte filtered by the sensor array.” Final Office Action (p. 8). Applicant notes, however, that what was actually stated was that McDevitt describes using a barcode to “determine the identity of the sensor array, not a filter.” June 11, 2007 Amendment (p. 4). Applicant’s remarks and characterization of McDevitt are consistent with what is actually described by McDevitt, which explains that “the reading device may be a bar code reader which is configured to read a bar code placed on the sensor array. In this manner the controller can read the bar code to determine the identity of the sensor array without any input from the user.” McDevitt (para. 573) (emphasis added). In other words, the bar code described by McDevitt is used for determining the identity of the sensor array to determine whether the correct type of sensor is being utilized. Consequently, McDevitt does not disclose, teach or suggest that the barcode on the sensor array is in any way related to a filter since, as described by McDevitt, the bar code is used for the specific purpose of identifying the sensor array to determine whether the correct sensor array is being used. In fact, paragraph 573 does not even refer to a filter. Thus, the basis of the rejection is not clear given these deficiencies.

Further deficiencies of the cited reference are evident from the description of how different types of data are acquired. In particular, paragraph 573 of McDevitt states that the controller will “require the identity of the sensor array and the test being performed.” McDevitt (para. 573). The following sentences in paragraph 573 explain that certain data is 1. input by a user, or 2. determined from a barcode on a sensor array. More specifically, McDevitt explains that “information concerning the sample” and “the type of test being performed” can be input by a user. In contrast, “the identity of the sensor array” may be determined from a barcode on the sensor array. McDevitt (para. 573) (emphasis added).

Consequently, the Office Action’s allegation that paragraph 573 of McDevitt describes a substrate or sensor array having “a bar code for identifying the contents of the wells” is not accurate since McDevitt specifically explains that “information concerning the sample” may instead be input by a user. Moreover, the Office Action’s characterization of paragraph 573 of McDevitt as describing a substrate or sensor array having “a bar code for . . . relaying test protocols to a computer” clearly is not supported by McDevitt since the cited reference specifically explains that the barcode is used for the purpose of identifying the sensor array, i.e., to determine whether the correct type of sensor array is being utilized, whereas a user may manually input “the type of test

being performed.” Therefore, McDevitt fails to disclose, teach or suggest the combination of “a data storage device attached to or positioned within the container” and “wherein data related to the filter is stored in the data storage device” as recited in claims 1 and 18 and wherein such data related to the filter “can be retrieved from” the data storage device as recited in claim 18.

Further, simply because an ADD may be coupled to a computer does not disclose, teach or suggest a data storage device attached to or positioned within the container, wherein data related to the filter is stored in the data storage device and can be retrieved there from by the processor through the communications interface, particularly considering that McDevitt explains that “information concerning the sample” and “the type of test being performed” can be input by a user, whereas “the identity of the sensor array” may be determined from a barcode on the sensor array for purposes of determine whether the correct sensor array is being utilized. McDevitt (para. 573).

In view of these deficiencies and clarifying remarks, Applicant respectfully submits that independent claims 1 and 18 are novel over McDevitt. Dependent claims 2-6, 11, 12, 14, 15, 19-23, 29-31, 33, 34 and 36-42 incorporate the elements and limitations of respective independent claims 1 and 18 and, therefore, are also allowable. MPEP §2143.03.

Further, the deficiencies of McDevitt relative to dependent claims 2 and 19 are discussed above. McDevitt explains that “information concerning the sample” and “the type of test being performed” can be input by a user, whereas “the identity of the sensor array” may be determined from a barcode on the sensor array for the purpose of determining whether the correct type of sensor is being utilized. McDevitt (para. 573).

McDevitt also fails to disclose, teach or suggest claims 6 and 23, which recite *inter alia* “the data storage device comprising a read/write memory.” It is alleged that a barcode is the “data storage device,” however, it is well known that a barcode is not a read/write device. If the rejection stands, Applicant respectfully requests the Examiner to explain how data can be written to a printed barcode as described by McDevitt and to evidence to that effect to support this allegation.

McDevitt also fails to disclose, teach or suggest “the stored data indicating a test or a combination of tests that is compatible with the filter” as recited in claims 11 and 30. In contrast, as discussed above, McDevitt explains that information concerning “the type of test being performed” can be input by a user. McDevitt (para. 573) (emphasis added). As is well understood, a user is not a barcode that stores data.

Moreover, McDevitt fails to disclose, teach or suggest “the stored data indicating a specimen that is compatible with the filter” as recited in claims 12 and 31. In contrast, the stored data identifies the sensor array. Paragraph 573 of McDevitt does not even refer to a filter.

McDevitt also fails to disclose, teach or suggest “the stored data indicating a number of processing steps involving the filter or the specimen” as recited in claims 14 and 33. It is conceded that McDevitt “does not explicitly disclose that the bar code disclosed by McDevitt et al. relays the number of steps involved in the test protocols . . .” Final Office Action (p. 4). It is generally alleged that “it is evident that the bar code relays this information.” Final Office Action (p. 4). However, as discussed above, McDevitt explains that “the identity of the sensor array” may be determined from a barcode on the sensor array. McDevitt (para. 573) (emphasis added).

Further, the Office Action essentially alleges that it is inherent that the barcode described by McDevitt stores data indicating a number of processing steps involving the filter or the specimen. MPEP §2131 (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”). Applicant notes the following inherency standards. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. MPEP §2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); MPEP §2163.07 (To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP §2112, citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). *See also*, *Akami Tech., Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1188 (Fed. Cir. 2003) (A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely

probably or possible present). In this case, the Examiner has provided to explanation that the subject matter of claims 14 and 33 are necessary present in McDevitt. Moreover, the Examiner has provided no extrinsic evidence to this effect. Accordingly, the “inherency” allegations concerning claims 14 and 33 cannot stand, particularly considering that McDevitt explains that information concerning “the type of test being performed” can be input by a user. McDevitt (para. 573) (emphasis added).

McDevitt also fails to disclose, teach or suggest “the stored data indicating one or more parameters of processing steps involving the filter or the specimen” as recited in claims 15 and 34. Rather, as discussed above, McDevitt explains that information concerning “the type of test being performed” can be input by a user. McDevitt (para. 573) (emphasis added).

Claim 39 and claims 40-42, which depend directly or indirectly from claim 39, are also rejected as allegedly being anticipated by McDevitt. Claim 39 recites *inter alia* “a vial for holding the biological specimen sample, wherein the vial and the filter each includes a respective code.” The Office Action, however, has not identified a vial and has not identified a vial and a filter, both of which include a code. In fact, McDevitt does not even refer to “vial.”

Accordingly, Applicant respectfully requests that the rejection of claims 1-6, 11, 12, 14, 15, 18-23, 29-31, 33, 34 and 36-42 under 35 U.S.C. §102(b) as allegedly being anticipated by McDevitt be withdrawn.

#### **IV. Claims 16, 17, 35, 43, 57 and 58 Are Patentable Over McDevitt**

Dependent claims 16, 17, 35, 43, 57 and 58 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt. Dependent claims 16, 17, 35, 43, 57 and 58 incorporate the elements and limitations of respective independent claims 1 and 18 and, therefore, are also allowable in view of the deficiencies of McDevitt discussed above. MPEP §2143.03.

It is generally alleged that the system described by McDevitt processes blood samples and, therefore, that it would have been obvious to use a cytological filter. Applicant notes, however, that McDevitt explains that analysis of bodily fluids “will, typically, require a filtration of the material prior to analysis. For example, cellular material and proteins may need to be removed from the bodily fluids.” McDevitt (para. 464) (emphasis added). Accordingly, McDevitt does not disclose, teach or suggest a cytological filter for collecting and examining cells of the biological specimen as recited in claims 17, 43 and 56.

Moreover, given the particular use of a filter as described by McDevitt, the cited reference teaches away from claims 17, 43 and 56.

Additionally, McDevitt teaches away from a data storage device attached to or positioned within the container and “wherein data related to the filter is stored in the data storage device” as recited in claims 1 and 18 and wherein such data related to the filter “can be retrieved from” the data storage device as recited in claim 18 since the specific purpose of the bar code on the sensor array is to determine **the identity of the sensor array** for the purpose of determining whether the correct sensor array is being utilized. McDevitt (para. 573) (emphasis added).

Accordingly, Applicant respectfully requests that the rejection of claims 16, 17, 35, 43, 57 and 58 under 35 U.S.C. §103(a) be withdrawn.

#### **V. Claims 8-10 and 25-28 Are Patentable Over McDevitt and Marsh**

Dependent claims 8-10 and 25-28 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt in view of U.S. Patent No. 5,219,294 to Marsh *et al.* (“Marsh”). Marsh is cited for the limited purpose of allegedly disclosing certain connectors and connector configurations. Accordingly, the cited references, individually and in combination, cannot support the rejection. MPEP §2143.03.

Further, the Office Action has not identified a data storage device (as recited in claims 1 and 18) that is within a recess of a container as recited in claims 8 and 25. Applicant notes that claims 8 and 25 recite: 1. a container defining a recess; 2. a data storage device (that stores data related to a filter), and 3. that the data storage device is positioned in the recess. In other words, claims 8 and 25 do not merely recite a connector. Rather, claims 8 and 25 recite that the data storage device is positioned in a recess of a container. For example, Fig. 2B of the subject application illustrates a data storage device 130 that is positioned within a recess 134 of a filter tray 110.

It is generally alleged that it would be obvious to design an interface connection in view of the lap top - desk top connector described by Marsh. Marsh, however, does not disclose, teach or suggest, and is not related to, a data storage device that stores filter data. In this regard, Marsh is not analogous art.

More specifically, to rely on a reference under 35 U.S.C. §103(a), the reference must either 1. be in the field of Applicant’s endeavor, or 2. be reasonably pertinent to the particular problem with which the inventor is concerned. MPEP §2141.01(a). A connector for

interconnecting a lap top computer and a desk top computer is not in the field of endeavor of preparing biological specimens. Accordingly, Marsh must be reasonably pertinent to the particular problem with which the inventor is concerned. As discussed in the “Description of Related Art,” Applicant describes, *e.g.*, improving systems that utilize cytological filters by verifying filter expiration, compatibility with specimens and availability of processing information and operating parameters. Marsh, in contrast, is not at all related to these unique cytology problems. In contrast, Marsh addresses a very different problem of providing a high density electrical connector between a lap top computer and a desk top computer. Marsh (col. 1, lines 9-11; 31-42). Consequently, Marsh is not analogous art for purposes of a rejection under §103(a).

Moreover, given the very different devices and applications described in McDevitt and Marsh, a person of ordinary skill in the art would not combine these unrelated references.

Additionally, McDevitt teaches away from a data storage device attached to or positioned within the container and “wherein data related to the filter is stored in the data storage device” as recited in claims 1 and 18 and wherein such data related to the filter “can be retrieved from” the data storage device as recited in claim 18 since the specific purpose of the bar code on the sensor array is to determine **the identity of the sensor array** for the purpose of determining whether the correct sensor array is being utilized. McDevitt (para. 573) (emphasis added).

Accordingly, Applicant respectfully requests that the rejection of claims 8-10 and 25-28 under 35 U.S.C. §103(a) be withdrawn.



## VI. Claims 13 and 32 Are Patentable Over McDevitt and Giordano

Dependent claims 13 and 32 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over McDevitt in view of Giordano. Giordano is cited for the limited purpose of allegedly disclosing filter expiration data. Giordano, however, does not cure the deficiencies of McDevitt. Accordingly, the cited references, individually and in combination, cannot support the rejection. MPEP §2143.03.

It is generally alleged that it would be obvious to add the expiration date of a filter to a data storage means of McDevitt. Final Office Action (p. 6). Giordano, however, is not analogous art. A meter system for a water treatment device is not in the field of Applicant's endeavor of preparing biological specimens. Accordingly, Giordano must be reasonably pertinent to the particular problem with which the inventor is concerned. As discussed in the "Description of Related Art," Applicant describes, e.g., improving systems that utilize cytological filters by verifying filter expiration, compatibility with specimens and availability of processing information and operating parameters. Giordano, in contrast, is not at all related to these unique cytology problems. In contrast, Giordano addresses very different problems related to a water treatment device that is attached to a faucet. Giordano (col. 1, lines 45-55). Consequently, Giordano is not analogous art for purposes of a rejection under §103(a).

Moreover, given the very different devices and applications described in McDevitt and Giordano, a person of ordinary skill in the art would not combine these unrelated references.

Additionally, McDevitt teaches away from a data storage device attached to or positioned within the container and "wherein data related to the filter is stored in the data storage device" as recited in claims 1 and 18 and wherein such data related to the filter "can be retrieved from" the data storage device as recited in claim 18 since the specific purpose of the bar code on the sensor array is to determine **the identity of the sensor array** for the purpose of determining whether the correct sensor array is being utilized. McDevitt (para. 573) (emphasis added).

Accordingly, Applicant respectfully requests that the rejection of claims 13 and 32 under 35 U.S.C. §103(a) be withdrawn.

**CONCLUSION**

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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